

*Quality review study information* means all documentation related to the quality review study process.

*Reviewer* means review coordinator, physician, or other person authorized to perform PRO review functions.

*Sanction report* means a report filed pursuant to section 1156 of the Act and part 474 of this chapter documenting the PRO's determination that a practitioner or institution has failed to meet obligations imposed by section 1156 of the Act.

*Shared health data system* means an agency or other entity authorized by Federal or State law that is used by the PRO review system to provide information or to conduct or arrange for the collection, processing, and dissemination of information on health care services.

*Subcontractor* means a facility or a non-facility organization under contract with a PRO to perform PRO review functions.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

**§ 476.102 Statutory bases for acquisition and maintenance of information.**

(a) Section 1154(a)(7)(C) of the Act requires PROs to the extent necessary and appropriate to examine the pertinent records of any practitioner or provider of health care services for which payment may be made under Title XVIII of the Act.

(b) Section 1154(a)(9) of the Act requires PROs to collect and maintain information necessary to carry out their responsibilities under the Act.

(c) Section 1156(a)(3) of the Act requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services they provide to Medicare patients as required by PROs.

**§ 476.103 Statutory bases for disclosure of information.**

(a) Section 1154(a)(10) of the Act requires PROs to exchange information with intermediaries and carriers with contracts under sections 1816 and 1842 of the Act, other PROs, and other public or private review organizations as appropriate.

(b) Section 1160 of the Act provides that PRO information must be held in confidence and not be disclosed except where—

(1) Necessary to carry out the purpose of Title XI Part B of the Act;

(2) Specifically permitted or required under this subpart;

(3) Necessary, and in the manner prescribed under this subpart, to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse;

(4) Necessary, and in the manner prescribed under the subpart to assist Federal or State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health;

(5) Necessary, and in the manner prescribed under this subpart, to assist appropriate State agencies having responsibility for licensing or certification of providers or practitioners; or

(6) Necessary, and in the manner prescribed under this subpart to assist Federal or State health planning agencies by furnishing them aggregate statistical data on a geographical, institutional or other basis.

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**§ 476.104 Procedures for disclosure by a PRO.**

(a) *Notice to accompany disclosure.*

(1) Any disclosure of information under the authority of this subpart is subject to the requirements in § 476.105 relating to the providing of a notice of the disclosure.

(2) Disclosure of confidential information made under the authority of this subpart, except as provided in § 476.106, must be accompanied by a written statement informing the recipient that the information may not be redisclosed except as provided under § 476.107 that limits redisclosure.

(b) *PRO interpretations.* A PRO may provide a statement of comment, analysis, or interpretation to guide the recipient in using information disclosed under this subpart.

(c) *Fees.* A PRO may charge a fee to cover the cost of providing information authorized under this subpart. These

fees may not exceed the amount necessary to recover the cost to the PRO for providing the information.

(d) *Format for disclosure of public information.* A PRO is required to disclose public information (§476.120(a)(6)) only in the form in which it is acquired by the PRO or in the form in which it is maintained for PRO use.

(e) *Medicare provider number.* A PRO must include the provider identification number assigned by the Medicare program on information that HCFA requests.

**§ 476.105 Notice of disclosures made by a PRO.**

(a) *Notification of the disclosure of non-confidential information.* Except as permitted under §476.106, at least 30 calendar days before disclosure of nonconfidential information, the PRO must notify an identified institution of its intent to disclose information about the institution (other than reports routinely submitted to HCFA or Medicare fiscal intermediaries, or to or from PRO subcontractors, or to or from the institution) and provide the institution with a copy of the information. The institution may submit comments to the PRO that must be attached to the information disclosed if received before disclosure, or forwarded separately if received after disclosure.

(b) *Notification of the disclosure of confidential information.* (1) A PRO must notify the practitioner who has treated a patient, of a request for disclosure to the patient or patient representative in accordance with the requirements and exceptions to the requirements for disclosure specified under §476.132.

(2) A PRO must notify a practitioner or institution of the PRO's intent to disclose information on the practitioner or institution to an investigative or licensing agency (§§476.137 and 476.138) except for cases specified in §476.106 involving fraud or abuse or imminent danger to individuals or the public health. The practitioner or institution must be notified and provided a copy of the information to be disclosed at least 30 calendar days before the PRO discloses the identifying information. The PRO must forward with the information any comments submitted by the practitioner or institution

in response to the PRO notice if received before disclosure, or forwarded separately if received after disclosure.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

**§ 476.106 Exceptions to PRO notice requirements.**

(a) *Imminent danger to individuals or public health.* When the PRO determines that requested information is necessary to protect against an imminent danger to individuals or the public health, the notification required in §476.105 may be sent simultaneously with the disclosure.

(b) *Fraud or Abuse.* The notification requirement in §476.105 does not apply if—

(1) The disclosure is made in an investigation of fraud or abuse by the Office of the Inspector General or the General Accounting Office; or

(2) The disclosure is made in an investigation of fraud or abuse by any other Federal or State fraud or abuse agency and the investigative agency specifies in writing that the information is related to a potentially prosecutable criminal offense.

**§ 476.107 Limitations on redisclosure.**

Persons or organizations that obtain confidential PRO information must not further disclose the information to any other person or organization except—

(a) As directed by the PRO to carry out a disclosure permitted or required under a particular provision of this part;

(b) As directed by HCFA to carry out specific responsibilities of the Secretary under the Act;

(c) As necessary for HCFA to carry out its responsibilities for appeals under section 1155 of the Act or for HCFA to process sanctions under section 1156 of the Act;

(d) If the health care services furnished to an individual patient are reimbursed from more than one source, these sources of reimbursement may exchange confidential information as necessary for the payment of claims;

(e) If the information is acquired by the PRO from another source and the receiver of the information is authorized under its own authorities to acquire the information directly from the